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U.S. Nuclear Regulatory Commission Attn: Document Control Desk Washington, D.C. 20555-0001

Reply to a Notice of Violation and a Notice of Nonconformance

Reference: Letter, J. Peralta (NRC) to G. Bryant (B&W), dated October 15, 2008, "NRC Inspection Report No. 99900042/2008-201, Notice of Violation, and Notice of Nonconformance."

Babcock & Wilcox's reply to a Notice of Violation and a Notice of Nonconformance are enclosed in Attachment A. As discussed in the attachment, we have already taken some of the corrective actions and others are currently in process. We are confident that these corrective actions will prevent further violations and nonconformances in these areas.

Babcock & Wilcox views this matter with the utmost seriousness and we are committed to the courses of action described in this reply.

Yours truly, BABCOCK & WILCOX NUCLEAR OPERATIONS GROUP, INC.

Gary Bryant Quality Control Manager

Enclosure: Attachment A

cc: Juan Peralta, Chief Quality and Vendor Branch 1 Division of Construction Inspection and Operational Programs



Attachment A

Babcock & Wilcox Nuclear Operations Group's Reply to NRC Notice of Violation and Notice of Nonconformance NRC Inspection Report 99900042/2008-201

1. Notice of Violation 99900042/2008-201-01

Violation 99900042/2008-201-01 states that B&W's 10 CFR Part 21 implementing procedure (NE/C-1716-04-Q) did not include guidance for: (1) evaluating deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards within 60 days of discovery, (2) providing an interim report to the Commission if the evaluation cannot be completed within 60 days of discovery, (3) notifying the responsible officer within five days when it is determined that a defect that could cause a substantial safety hazard exists, (4) notifying customers in 5 days if the supplier determines that it cannot perform the evaluation of a deviation, (5) notifying the Commission by fax or telephone within 2 days of the director being notified of a defect, and (6) providing written notification to the Commission within 30 days of the initial notification.

Babcock & Wilcox Reply to Notice of Violation 99900042/2008-201-01

Reason for the Violation:

B&W had an incomplete understanding of the 10 CFR Part 21 evaluation and reporting timeline requirements. Additionally, B&W had one procedure, NE/C-1716-04-Q, for evaluating and reporting deviations for both 10 CFR Part 21 requirements and Ohio Department of Health (ODH 3701) requirements. The requirements for the two codes are different and incorporating the two into one procedure resulted in some confusion.

Corrective Steps Taken:

The procedure, NE/C-1716-04-Q, was rewritten to cover only the 10 CFR Part 21 requirements, and it now includes guidance for items 1-6 identified in the violation.

Corrective Steps to Avoid Further Violations:

Training will be performed, as required, to ensure an understanding of the NE/C-1716-04-Q procedure and the evaluation and reporting requirements of 10 CFR Part 21.

Date When Full Compliance will be Achieved:

Corrective actions and associated training will be completed by 12/31/2008.

2. Notice of Nonconformance 99900042/2008-201-02

Nonconformance 99900042/2008-201-02 states that contrary to Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to Title 10 Part 50 and Supplement 7S-1 to NQA-1-1994, "Supplementary Requirements for Control of Purchased Items and Services," B&W procured safety-related weld wire from AREVA NP Inc. in 2007 without sufficient documented evidence of AREVA NP Inc.'s capability to provide items or services in accordance with the technical and quality requirements of the purchase documents. Additionally, the B&W Procedure NE/C-1722-02-Q, "Supplier Evaluations," Revision 4, dated May 27, 2008, allowed the Supplier Quality Department to procure from a supplier without sufficient evaluation of the implementation of the supplier's QA program.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-02

Reason for the Noncompliance:

B&W was unaware that the NRC had issued Information Notice 86-21 which took exception to the statement in ASME Section III NCA-3561, "Certificate Holders whose scope includes the supply or manufacture of materials need not be surveyed or audited for work or material covered by the scope of their certificate."

Corrective Steps Taken:

B&W now requires relevant managers to subscribe to the NRC's e-mail distribution list for all notices that the NRC publishes. This will assist the relevant managers in receiving current information and maintaining their knowledge base.

B&W will also review all purchase orders issued to N certificate holders to determine the extent to which they do not comply with the requirements of Supplement 7S-1 to NQA-1-1994.

B&W will perform and document the evaluation of AREVA NP Inc., and any other supplier that is identified as a result of the review performed in accordance with the requirements of Appendix B to Title 10 Part 50 and Supplement 7S-1 to NQA-1-1994. The evaluations will be assessed to determine whether other changes are necessary.

Corrective Steps to Avoid Further Noncompliances:

B&W will revise Policy Number 12-QA-07 of the B&W QA Manual and procedure NE/C-1722-02-Q to be in compliance with Appendix B to Title 10 Part 50 and Supplement 7S-1 to NQA-1-1994.

B&W will provide training to all related personnel on the revisions of the above procedures.

Date When Corrective Action will be Completed:

The review of the purchase orders will be completed by 2/15/2009.

The policy and procedure will be revised, approved, and training completed by 3/15/2009.

3. Notice of Nonconformance 99900042/2008-201-03

Nonconformance 99900042/2008-201-03 states that contrary to Criterion VII and XI of Appendix B 10 CFR Part 50, Policy Number 12-QA-07 of the B&W Quality Assurance Program Manual (QAPM), "Control of Purchased Items and Services," Revision 10, dated January 28, 2008, and B&W Procedure NE/C-1722-02-Q, B&W procured and used thermocouples from a supplier not listed on the B&W Approved Suppliers List, Revision 27, dated August 27, 2008 and did not evaluate the supplier before the procurement.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-03

Reason for the Noncompliance:

The cause of the violation was a failure to recognize the certification and calibration of the wire was required to be performed either internally by means of the B&W M&TE (Measurement & Test Equipment) Calibration

program or, by a vendor on the Approved Suppliers List since the wire was being used on a safety-related component.

The thermocouple wire identified within this nonconformance was supplied with a Calibration Laboratory Test Report traceable to the National Institute of Standards & Technology, and their calibration system is in compliance with ISO/IEC 17025.

Corrective Steps Taken:

Immediately upon discovery of the nonconforming condition on 8/28/2008, a sample from each end of the unused portion of the thermocouple wire was expedited to a local vendor on our Approved Suppliers List for testing. Testing was performed and completed with calibration test reports being supplied on 8/29/2008, which verified the wire to be acceptable.

Corrective Steps to Avoid Further Noncompliances:

Administrative Procedure NE/C-1211-13-Q, "Purchase, Certification, and Release System for Thermocouple Wire and Assemblies", will be revised to assure that if thermocouple wire is not supplied by a vendor on the Approved Suppliers List, provisions are in place to assure the thermocouple wire calibration performed either internally by means of the B&W M&TE Calibration program or, by a vendor on the Approved Suppliers List, and verified to be acceptable prior to being released.

A stop notice has been placed in current processes at operations requiring the use of thermocouple wire. The stop notice will require verification of the proper certification to assure that this nonconformance is not repeated prior to the procedure being revised.

Date When Corrective Action will be Completed:

NE/C-1211-13-Q will be revised, approved, with training on those revisions to related personnel completed by 1/15/2009.

4. Notice of Nonconformance 99900042/2008-201-04

Nonconformance 99900042/2008-201-04 states that contrary to Criterion VII of Appendix B 10 CFR Part 50 and Policy Number 12-QA-07 of the B&W QAPM, B&W Procedure NE/C-1711-02-Q did not include guidance for granting a source inspection waiver on a purchase order in which source inspections were originally required. Furthermore, B&W failed to conduct a source inspection for nine purchase orders from Westmoreland Mechanical Testing in which source inspections were required to be performed. Further, Source Inspection/Waiver Request forms documenting a waiver of the source inspection were not available or retrievable.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-04

Reason for the Noncompliance:

Procedure NE/C-1711-02-Q addresses instructions for waived inspections of dimensional inspections only.

There is no method or system employed by Purchasing to monitor status of receiving source waiver requests.

The supplier was unfamiliar with B&W's purchase order requirements.

Corrective Steps Taken:

For the identified conditions, the work is complete, and the witness is not recoverable.

Corrective Steps to Avoid Further Noncompliances:

NE/C procedure will be revised to include instructions for waived inspections and guidance for waiving inspections for all weld consumables, calibration and test laboratory suppliers.

Standard Clause N10 and N79 will be reviewed and revised as applicable to address notification requirements pertaining to services that are to be performed and/or delivered (in lieu of hardware to be delivered).

All related personnel will be retrained regarding distribution of PO's containing Source Inspection Requirements, standard clauses N10 and N79.

Work Instruction PUR 1711-02-01, Supplier Source Inspection, will be strengthened to address the deficiencies that were observed. Revisions to the instructions may include all or some of the following examples: explicit requirements for (a) Buyers to conduct, and formally document, the review of the source placement, (b) Buyers to add the Notification Requirement as a separate line item in commercial nuclear orders for services that contain standard clause N10 or N79, and (c) Buyers to monitor their Buyer Status report and call suppliers when the source inspection due date draws near to assure that the Supplier complies with the purchase order requirement.

Date When Corrective Action will be Completed:

Corrective actions will be completed by 1/30/2009.

5. Notice of Nonconformance 99900042/2008-201-05

Nonconformance 99900042/2008-201-05 states that contrary to Criterion XII, "Control of Measuring and Test Equipment," of Appendix B 10 CFR Part 50, Policy Number 12-QA-12 of the B&W QAPM, "Control of Measuring and Test Equipment," Revision 10, dated January 28, 2008, B&W Gage Room Operational Manual (GROM), "Gage Control," Revision 20, dated February 12, 2008, B&W Technical Procedure 12-3-GEM-8, "Calibration of Temperature Measuring Equipment," Revision 13, dated August 21, 2006, and B&W Technical Procedure 12-3-WQI-120, "Storage and Handling of Electrodes, Flux, and Filler Wire for Commercial ASME Contracts," Revision 1, dated August 29, 2005, B&W failed to implement its procedures to control measuring and test equipment as required. Specifically: (1) B&W extended the frequency of the calibration for the 2-inch - 12-inch inside diameter micrometer set for the second cycle without recalibrating the micrometer set, even though the micrometer set had been used during the first extended calibration. (2) B&W calibrated the commercial rod oven dial thermometer using one calibration point instead of a minimum of three calibration points. In addition, the thermometer's calibration failed to meet the temperature requirements specified in Technical Procedure 12-3-WQI-120.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-05

Reason for the Noncompliance:

The gage was not checked out properly in the gage room tracking system. The gage utilization system was not filled out in a timely manner. The time span between the use of the gage and the calibration due date were close enough to allow for this error. The gage usage was logged into the system after the gage had been calibrated, and extended due to non-usage per the GROM.

The checkout system is what should be used to control the use of gages. Currently the gage utilization section of the gage system is used to verify use of gages. This weakness allows for gages to be extended based on non-usage when in actuality the gage could have been used for in-process checks by shop floor personnel. Currently shop floor personnel do not have gage usage personnel numbers. These numbers are used in the gage tracking system for checking out gages from the gage room.

Failure to properly interpret procedure 12-3-GEM-8 led to noncompliance pertaining to the thermometer calibration.

Corrective Steps Taken:

The gage has been properly calibrated and found to be acceptable. The calibration card has been updated to reflect the current calibration. Until such time that the preventative corrective action is completed, no gage calibrations will be extended based on usage without the approval of the Inspection Supervisor. Training will be conducted with all gage room personnel to preclude calibration extensions.

Re-Calibrate Commercial Rod oven thermocouples per 12-3-GEM-8. Prior to this calibration, the technician will be re-trained on the requirements of 12-3-GEM-8. Recalibration will follow the requirements of section 6.4 which will satisfy 12-3-WQI-120. The mid range of the thermocouple being calibrated is 300 deg. F, which falls into the range of 225-300 deg. F required by 12-3-WQI-120 for baking of commercial welding rods.

Corrective Steps to Avoid Further Noncompliances:

In the future the check out system will be used to verify gage usage instead of the gage utilization section of the gage system. Training will be conducted on the proper way to verify gage usage and the allowance for extending gage calibrations. All shop floor personnel will be assigned a gage utilization personnel number. Gages will be properly tracked in the gage system i.e. checked in and out each time a gage is used or removed from the gage room.

Train all technicians on requirements of 12-3-GEM-8 to provide clarity.

Date When Corrective Action will be Completed:

The gage utilization training will be completed 3/01/2009. Training on the requirements of 12-3-GEM-8 was completed on 10/31/08.

6. Notice of Nonconformance 99900042/2008-201-06

Nonconformance 99900042/2008-201-06 states that contrary to Criterion XIII, "Handling, Storage, and Shipping," of Appendix B 10 CFR Part 50, Policy Number 12-QA-13 of the B&W QAPM, "Handling, Storage, and Shipping," Revision 8, dated January 28, 2008, B&W Technical Procedure 12-3-GEM-3, "Procedure for Material Handling, Equipment Design, Inspection, Maintenance and Use," Revision 8, dated September 12, 2005, and B&W Technical Procedure NDE(G)-1710-38, "Magnetic Particle Inspection of Crane Hooks and Tooling," Revision 5, dated February 27, 2007, B&W failed to provide documented evidence that its preventive maintenance program had been effectively implemented and failed to adopt and implement adequate procedures to control handling equipment as required. Specifically: (1) B&W lacked documented evidence of annual maintenance and magnetic particle examination performed on two crane hooks and two beams. (2) B&W Technical Procedures 12-3-GEM-3 and NDE (G)-1710-38 failed to address the requirement for documenting and maintaining records.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-06

Reason for the Noncompliance:

Procedure 12-3-GEM-3 fails to address documentation of inspections.

Corrective Steps Taken:

B&W will revise 12-3-GEM-3 to include appropriate inspection forms.

Corrective Steps to Avoid Further Noncompliances:

B&W will develop inspection forms covering inspection of various types of lift equipment. Forms will list inspection criteria, equipment inspected, and any action taken to address issues, and will require the inspector to sign and date the inspection form.

B&W implemented the use of new forms for all other lift equipment under the quarterly inspection cycle that started on 10/31/2008.

Date When Corrective Action will be Completed:

The revision of the procedure will be completed by 1/31/2009.

7. Notice of Nonconformance 99900042/2008-201-07

Nonconformance 99900042/2008-201-07 states that contrary to Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B 10 CFR Part 50 and Policy Number 12-QA-15 of the B&W QAPM, "Control of Nonconforming Items," Revision 9, dated January 28, 2008, B&W failed to establish and implement procedures to notify affected organizations, including suppliers and customers, of nonconforming conditions. Specifically: (1) B&W had not established any written procedures for the notification of suppliers when a nonconforming condition was discovered at the B&W facility during receipt inspection. (2) B&W policies and procedures lacked controls for notifying its customers of nonconforming conditions on procured items.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-07

Reason for the Noncompliance:

B&W lacked a written procedure for supplier and customer notification of nonconformances. Current procedures for non-conforming conditions do not address the requirements for notifications of suppliers or customers when a non-conforming condition is discovered

Corrective Steps Taken:

A new procedure will be developed or one or more existing procedures will be revised to ensure suppliers and customers are informed of any nonconformance that is discovered during receipt inspections of supplied materials or procured items.

Corrective Steps to Avoid Further Noncompliances:

Upon completion of the new or revised procedures training sessions will be performed with all pertinent personnel. The training will be documented on the B&W Indoctrination and Training Record.

Date When Corrective Action will be Completed:

The corrective action will be completed by 3/1/2009.

8. Notice of Nonconformance 99900042/2008-201-08

Nonconformance 99900042/2008-201-08 states that contrary to Criterion XVI, "Corrective Action," of Appendix B 10 CFR Part 50 and Policy Number 12-QA-16, "Corrective Action," Revision 10, dated January 28, 2008, of the B&W QAPM, B&W failed to document all nonconformances related to activities such as internal audits, customer audits, or surveys in CARs. The NRC inspectors found that none of the eight findings identified by a customer's audit were entered into B&W's corrective action program. Additionally, since September 2007, the same customer issued five condition reports to B&W. The NRC inspectors found that only one of these condition reports was captured in a CAR.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-08

Reason for the Noncompliance:

Section 5.0 of Policy 12-QA-15 Rev. 9 states, "Nonconformances related to activities such as internal audits, customer audits, or surveys shall be documented on a corrective action request form." In the case of the customer's audit findings and condition reports, this requirement was overlooked by the QA Department at the time of issuance of these findings/conditions.

Corrective Steps Taken:

B&W will issue a CAR (Corrective Action Request) for each of the eight customer audit findings, and the four customer condition reports.

Corrective Steps to Avoid Further Noncompliances:

A "Mt Vernon" only CAR database has been established to track Corrective Action Requests, and a CAR Database Administrator has been established.

In addition to the above, at the weekly Quality Department meeting, audits and CARs are discussed among other agenda items.

Date When Corrective Action will be Completed:

All CAR's have been issued.

9. Notice of Nonconformance 99900042/2008-201-09

Nonconformance 99900042/2008-201-08 states that contrary to Criterion XVI, "Corrective Action," of Appendix B 10 CFR Part 50, Policy Number 12-QA-16 of the B&W QAPM, and B&W Procedure NE/C-1717-03-Q, "Corrective Action," Revision 3, dated July 8, 2008, B&W failed to perform any trending on: (1) the results of internal and external audits, or (2) CARs related to B&W's ASME QA program or the Diablo Canyon Replacement Vessel Head being manufactured at B&W.

Babcock & Wilcox Reply to Notice of Nonconformance 99900042/2008-201-09

Reason for the Noncompliance:

The available trending tool was inadequate for assessing trends in the B&W ASME program. The tool provided too few categories, and, therefore, provided limited potential trend analysis. Trending had not been performed based on the understanding that the available tool would not provide adequate trending data and a lack of sufficient data to perform an analysis.

Corrective Steps Taken:

The trending tool will be evaluated and a tool will be developed to produce adequate trend analysis. A trend analysis will be executed upon completion of the trending tool.

Corrective Steps to Avoid Further Noncompliances:

B&W will perform training on the use of the trending tool. A procedure will be developed to ensure periodic trend analysis.

Date When Corrective Action will be Completed:

The corrective action will be completed by 5/1/2009.